

Colo., alleging that within the period from on or about February 13 to on or about May 8, 1941, the defendant had repacked and relabeled quantities of the above-named product while it was being held for sale after shipment in interstate commerce, which acts by the defendant resulted in misbranding of said drug. At the time of shipment the product was labeled: "5000 Capsules Acetylsalicylic Acid and Colchicine Compound (Formerly Called Roomatoan) Brown. Each capsule contains: Acetylsalicylic Acid . . . 5 grs. Macroton . . . ¼ gr. Phytolaccin . . . ½ gr. Colchicine . . . 1/300 gr. Caution: These capsules are to be used only by or on the prescription of a physician." After repackaging and relabeling it was labeled: "One Capsule Every hour for 4 doses Then One Every 4 hours Sam Frank Drug Co. Colfax at Downing—Denver Keystone 3217."

The article when repacked and relabeled was misbranded: (1) In that it contained colchicine, the frequent or continued use of which might result in abdominal pain (stomach ache, cramps, colic), nausea, vomiting, diarrhea, or bloody urine, and in that the statements on the label failed to bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users. (2) In that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient.

On March 16, 1942, the defendant entered a plea of guilty and the court imposed a fine of \$10.

661. Misbranding of Nichol's Long Life For Health and Dickson's Laxative Diuretic. U. S. v. James B. Nichols (J. B. Nichols & Sons and Nichols Chemical Co.). Plea of guilty. Fine of \$100 and jail sentence of 6 months. Sentences suspended and defendant placed on probation for 3 years. (F. D. C. No. 5475. Sample Nos. 39561-E, 39562-E.)

The labeling of the Laxative Diuretic failed to bear adequate warning statements; that of both products bore false and misleading therapeutic claims and inadequate ingredient and quantity of contents statements. The bottles containing both products were paneled in such manner as to be deceptive.

On January 26, 1942, the United States attorney for the Western District of Tennessee filed a libel against James B. Nichols, trading as J. B. Nichols & Sons, and as Nichols Chemical Co. at Memphis, Tenn., alleging shipment on or about November 12, 1940, from the State of Tennessee into the State of Arkansas of quantities of the above-named products that were misbranded.

Analyses of samples of the products showed that Nichol's Long Life for Health consisted of extracts of plant drugs, alcohol (13.0 percent by volume), and water; and that Dickson's Laxative Diuretic consisted essentially of Epsom salt, small proportions of caramel, methenamine, hyoscyamine, salicylic acid, sulfuric acid, and benzoic acid, minute amounts of strychnine and saccharin, and water.

Dickson's Laxative Diuretic was alleged to be misbranded: (1) In that its labeling did not bear adequate warnings against use in those pathological conditions where its use might be injurious to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since its labeling did not bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence on laxatives. (2) In that statements appearing on the bottle label which represented that each bottle contained 8 ounces of the drug, that it was efficacious as an aid in eliminating and correcting disorders of the alimentary canal and urinary organs, and that it would be efficacious in the treatment of biliousness, headache, gas on the stomach, and backache, were false and misleading since each bottle did not contain 8 ounces of the drug, but did contain a smaller amount, it was not efficacious as an aid in eliminating or correcting disorders of the alimentary canal or urinary organs and it would not be efficacious in the treatment of biliousness, gas on the stomach, or backache. (3) In that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the quantity or proportion of hyoscyamine and strychnine, since (a) the declaration of "hyeciamus" was meaningless; (b) the label bore no statement of the quantity or proportion of strychnine; and (c) it failed to bear the common or usual name of methenamine since the designation "Utropian," appearing on the label, is not the common or usual name of methenamine. (4) In that it was in package form and the labeling failed to bear an accurate statement of the quantity of contents in terms of measure. (5) In that its container (bottle) was so made and formed as to be misleading.

Nichol's Long Life for Health was alleged to be misbranded: (1) In that statements on the bottle label representing that it would be efficacious to prolong

life; to maintain health, and that it would be efficacious for colds in the chest; nervousness, weakness, and all cold conditions of the system that cause consumption, were false and misleading since it would not be efficacious for such purposes. (2) In that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient including the quantity, kind, and proportion of alcohol that it contained. (3) In that it was in package form and did not bear a label containing the name and place of business of the manufacturer, packer, or distributor. (4) In that it was in package form and did not bear a label containing an accurate statement of the quantity of contents in terms of measure. (5) In that its container was so made, formed, or filled as to be misleading.

On February 10, 1942, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of \$100 and a jail sentence of 6 months. Payment of the fine and the jail sentence were suspended and the defendant was placed on probation for 3 years.

662. Misbranding of SMH Pur-Erb Compound No. 1 and "Helena" Pur-Erb Special No. 3. U. S. v. James M. Odell (Home Treatment Service). Plea of guilty. Fine, \$25. (F. D. C. No. 5578. Sample Nos. 31963-E, 31964-E.)

The labels of both of these products failed to bear adequate directions for use and did contain false and misleading therapeutic claims; and the label for "Helena" Pur-Erb Special No. 3 failed to bear the required quantity of contents and ingredient statements. The label of the SMH Pur-Erb Compound also failed to bear adequate warning statements; it contained representations in certain foreign languages but failed to bear the required quantity of contents and ingredient statements in those foreign languages.

On February 27, 1942, the United States attorney for the Northern District of Illinois filed a libel against James M. Odell trading as Home Treatment Service at Chicago, Ill., alleging shipment on or about December 17, 1940, from the State of Illinois into the State of Indiana of quantities of the above-named products that were misbranded. The articles were labeled in part: "SMH Pur-Erb Compound No. 1 (Formerly Pur-Erb Tonic No. 1) * * * Prepared Only by Pur-Erb Products, Chicago, Ill." and "'Helena' Pur-Erb Special No. 3 * * * Kid-Ne Herb Compound * * * Herbal Health Products * * * Chicago."

Analyses of samples of the articles showed that SMH Pur-Erb Compound consisted essentially of extracts of plant drugs including laxative drugs such as aloes, senna, and cascara sagrada, and water; and that "Helena" Pur-Erb Special consisted essentially of extracts of plant drugs, solid plant material, and water.

SMH Pur-Erb Compound was alleged to be misbranded: (1) In that its label failed to bear adequate directions for use since those on the bottle label were indefinite as to amount. (2) In that the labeling failed to bear adequate warnings against unsafe methods or duration of administration in such manner and form as are necessary for the protection of users since it did not bear a warning that frequent or continued use might result in dependence on laxatives. (3) In that statements in the labeling representing and suggesting that it was efficacious in the treatment of chronic constipation; that it was a health prescription and would improve the general health; that it was an adequate remedy for constipation and colitis; and that it was efficacious in the treatment of serious, stubborn, obstinate or severe cases of constipation or colitis, were false and misleading since it would not be efficacious for such purposes. (4) In that certain information required by the act to appear on the label or labeling was not prominently placed thereon in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use since the label contained representations in foreign languages, namely, German, Polish, and Lithuanian, and by reason of said representations, it was labeled to appeal to persons understanding such foreign languages, and the label did not contain in said foreign languages an accurate statement of the quantity of the contents in terms of measure nor did said label bear in said foreign languages the common or usual name of each active ingredient.

"Helena" Pur-Erb Special was alleged to be misbranded: (1) In that the label failed to bear adequate directions for use since those given did not provide a limitation as to frequency and duration of its use. (2) In that the designation "Rx Kid-Ne Herb Compound" and the statements representing or suggesting that it was efficacious as a treatment of diseased conditions of the kidneys; that it was efficacious to overcome sluggish conditions of the genito-urinary system; that it was efficacious in the treatment of scant or excessive flow of urine; that it would be efficacious in the treatment of pains, aches, distresses and disturb-